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## TRANSMITTAL LETTER TO THE UNITED STATES ATTORNEY'S DOCKET NUMBER 701039-52287 DESIGNATED/ELECTED OFFICE (DO/EO/US) U.S. APPLICATION NO. (If known, see 37 CFR 1.5) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED PCT/US2003/030466 25 September 2003 (25.09.2003) 27 September 2002 (27.09.2002) TITLE OF INVENTION METHODS AND COMPOSITIONS FOR TREATMENT OF NEUROLOGICAL DISORDER APPLICANT(S) FOR DO/EO/US CHILDREN'S MEDICAL CENTER CORPORATION and BENOWITZ, Larry I. Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: 11. X An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. X A preliminary amendment. An Application Data Sheet under 37 CFR 1.76. A substitute specification. A power of attorney and/or change of address letter. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825. A second copy of the published International Application under 35 U.S.C. 154(d)(4). A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). Copy - Published PCT Cover Sheet - WO 2004/028468 A3; Copy - PCT/IB/306; Copy - PCT/IB/308; Copy - PCT/ISA/210 & 220;

Other items or information: References A1 & A2; Express Mail Cert. Label No. EL 948121594 US; Check - \$715.00; Return Receipt Postcard. This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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# JC12 Rec'd PCT/PTC 21 MAR 2005

PTO-1390 (Rev. 02-2005)
Approved for use through 3/31/2007. OMB 0651-0021
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ICATION NO. (if known, see 37 CFR 1.5)

INTERNATIONAL APPLICATION NO.

| U.S. APPLICAT  | TON NO. (if know                           | ·                                       | international A   | APPLICATION NO.          | ATTORNEY'S DOC              | KET NUMBER    |
|--|--|---|---|--------------------------|-----------------------------|---------------|
|  | 10/52                                      | 8685                                    | PCT/US20  | 03/030466                | 701039-5                    | 5228.7        |
| The fol  | lowing fees have b                         |   | <del></del>   |                          | CALCULATIONS                | PTO USE ONLY  |
| 21. 💢 Bas  | ic national fee                            | • | ···········   | \$300                    | \$ 300.00                   |               |
| 22. X Examination fee  If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)  |  |   |   |                          | \$ 200.00                   |               |
|  | 115  |   | ••••••  | \$200                    |                             | · · ·         |
| 23. Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority   |  |   |   |                          | \$ 500.00                   |               |
| TOTAL OF 21, 22 and 23 =   |  |   |   |                          | \$ 1,000.00                 |               |
| Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium).  The fee is \$250 for each additional 50 sheets of paper or fraction thereof. |  |   |   |                          |                             | . A           |
| Total Sheets   | Extra Sheets                               | thereof (round                          | n additional 50 or fraction<br>up to a whole number)          | RATE                     | *                           |               |
| 57 - 100 =   | -43 <sub>/50</sub> =                       |   | •   | x \$250                  | \$ 0.00                     |               |
| Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)).   |  |   |   |                          | \$ 130.00                   |               |
| CLAIMS   | NUME                                       | BER FILED                               | NUMBER EXTRA  | RATE                     | \$ .                        |               |
| <ul> <li>Total claims</li> </ul>   | <b>Y</b>                                   | 26 - 20 =                               | 6   | × \$50                   | \$ 300.00                   |               |
| Independent clai   | ms   | 3 -3=                                   | 0   | x \$200                  | \$ 0.00                     |               |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360  |  |   |   |                          | \$ 0.00                     |               |
| TOTAL OF ABOVE CALCULATIONS =  |  |   |   |                          | \$ 1,430.00                 |               |
| Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.  |  |   |   |                          | 715.00                      |               |
|  |  |   |   | SUBTOTAL =               | \$ 715.00                   | ·             |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).  |  |   |   |                          | \$                          | 0.00          |
| TOTAL NATIONAL FEE =   |  |   |   |                          | \$                          | 715.00        |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +   |  |   |   |                          | \$                          | 0.00          |
| TOTAL FEES ENCLOSED =  |  |   |   |                          | \$                          | 715.00        |
|  |  |   | <del> </del>  |                          | Amount to be refunded:      | \$.           |
|  |  |   |   |                          | Amount to be charged:       | \$            |
| a. X A chec  | k in the amount of                         | * \$                                    | 00 to cover the ab  |                          |                             |               |
|  | charge my Depos<br>cate copy of this s     |   |   | f \$ to co               | over the above fees.        |               |
| c. X The Co  | mmissioner is here<br>t No. <u>50-0850</u> | eby authorized to<br>A duplicate cop    | charge any additional fees v<br>by of this sheet is enclosed. | vhich may be required,   | or credit any overpaymen    | t to Deposit  |
| d. Fees ar<br>be incl  | e to be charged to                         | a credit card. Wan. Provide credit c    | ARNING: Information on this ard information and authorize     | s form may become put    | olic. Credit card informati | on should not |
| NOTE: Where ar   | n appropriate timestore the Intern         | e limit under 37<br>ational Applicati   | CFR 1.495 has not been mon to pending status.                 | et, a petition to revive | (37 CFR 1.137(a) or (b))    | must be filed |
| BENDALSCOR   | BESEKONDENCE                               | TO:                                     |   | . 1//                    | <u></u>                     |               |
|  | BODY LLP                                   |   |   |                          |                             |               |
| 100 Summer Street  |  |   |   |                          |                             |               |
| Boston, MA 02110-2131  David S. Re   |  |   |   |                          | Snick                       |               |
| US .   |  |   |   | 34,235                   | 211 111 125                 |               |
|  |  |   |   | REGISTRATIO              | ON NUMBER                   |               |

#### Practitioner's Docket No. 701039-52287

**PATENT** 

### IN THE UNITED STATES RECEIVING OFFICE

| International Application Number | International Filing Date | International Earliest Priority Date |  |
|----------------------------------|---------------------------|--------------------------------------|--|
| PCT/US2003/030466                | 25 September 2003         | 27 September 2002                    |  |
|                                  | 25.09.03                  | 27.09.02                             |  |

TITLE OF INVENTION:

METHODS AND COMPOSITIONS FOR TREATMENT OF

NEUROLOGICAL DISORDER

APPLICANTS FOR DO/US:

CHILDREN'S MEDICAL CENTER CORPORATION;

BENOWITZ, Larry I.

**INVENTORS FOR DO/US:** 

BENOWITZ, Larry I.

# VERIFIED CERTIFICATION OF EXPRESS MAILING DATE (INTERNATIONAL APPLICATION (37 C.F.R. section 1.10(c))

I declare that, on <u>March 21, 2005</u> I deposited, with the United States
Postal Service, in an envelope "Express Mail, Post Office to Addressee," bearing Label Number
EL 948 121 594 US, addressed to the "MAIL STOP PCT, Commissioner for Patents, P.O. Box 1450,
Alexandria, VA 22313-1450," and having an express mail certification that I executed, the following papers:

- 1. Transmittal Letter to the U.S. Receiving Office Concerning a Filing Under 35 U.S.C. 371 (in duplicate 4 pp.);
- 2. Application Data Sheet (5 pp.);
- 3. Preliminary Amendment (3 pp.);
- 4. Information Disclosure Statement (2 pp.);
- 5. Form 1449 (2 pp.);
- 6. References A1 & A2;
- 7. Form PCT/IB/308 (1 pg.);
- 8. Published PCT Cover Sheet WO 2004/028468 A3 (1 pg.);
- 9. International Search Report Forms PCT/ISA/220 & 210 (3 pp.);
- 10. Form PCT/IB/306 Notification of the Recording of a Change Attorney's Address (1 pg.);
- 11. Check \$ 715.00; and
- 12. Return Receipt Postcard.

A copy of these papers from the file of this application is attached.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

Date: 2/2/ . 2005

Nidole M. Aguirre

(type or print name of person certifying)